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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,970	08/29/2001	Ashok Rampal	RLL-170US	7742

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1615	15

DATE MAILED: 03/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/941,970	Applicant(s) RAMPAL ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 5-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 5-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgement of Papers Received: Change of Address entered 11/25/02, Power of Attorney entered 2/24/03, and After Final Request for Reconsideration entered 2/24/03.

Response to Arguments

1. Applicant's arguments, see pages 1-6, filed 2/19/03, with respect to the rejection(s)of claim(s) 1,2, and 5-12 under 35 USC 103 (a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Talwar et al (WO 00/15198) in view of Ayer et al (USPN 6,096,339) and Fuisz (USPN 5,518,730).

Double Patenting

2. Claims 1,2, 9 and 11 of this application conflict with claims 1-7, 18, 19 and 22 of Application No. 10/054,077. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1,2,9 and 11 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-7, 18, 19, and 22 of copending Application No. 10/054,077. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Claims 1, 2, and 9 of the present invention are drawn to a controlled dosage form of erythromycin derivative clarithromycin in a concentration of about 66 – 90 %, with a concentration of a rate controlling polymer from 0.1 – 4 % w/w. A possible rate-controlling polymer is recited to be a cellulose derivative. Claim 9 recited the polymer to be hydroxypropyl methylcellulose, or hydroxypropylcellulose. Claim 11 of the instant application is drawn to a monolithic dosage from comprising 1000 mg of clarithromycin where the total weight of the dosage unit is no more than 1500 mg.

Claims 1-7 of the copending application are drawn to a controlled dosage form comprising an antibiotic and rate-controlling polymer where the polymer is present in concentration from about 0.1% - 4.5% and the drug is present from about 10% - 90% w/w of the composition. The antibiotic is selected from a group consisting ciprofloxacin and erythromycin

and its derivatives. The polymer is recited as hydroxypropyl methylcellulose and other cellulose derivatives. Claims 18, 19 and 22 are drawn to monolithic dosages forms with 100 – 1300 mg of drug, where the total weight of the dosage unit is no more than 1500 mg, and 0.1% - 4.5% of rate-controlling polymers. The drug is recited to be clarithromycin.

One of ordinary skill in the art would have been motivated to follow the claims of the copending application to arrive at the invention of the instant application. The claims are identical in scope, and would be obvious to a skilled artisan to follow the claims of the copending application. An expected result of follow the claims would be a single dosage form of clarithromycin with low ranges of rate-controlling polymers.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 2, 5- 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Talwar et al (WO 00/15198) in view Ayer et al (USPN 6,096,339), Fuisz (USPN 5,518,730) and Misra et al (USPN 5,869,098). The claims recite a controlled release formulation of an antibiotic composition comprising low percentages of rate controlling polymers. Claim 5 – 10 recite the particular polymers, which are useful in the invention including cellulose derivatives, acrylic acid polymers, and polyuronic acid. Claim 11 recites a monolithic controlled release formulation. Claim 12 recites a process of preparing the formulation of the invention.

Talwar et al discloses a controlled release single dosage form comprising polymers. The dosage from is a single dosage form of the antibiotic ciprofloxacin. The dosage from also further comprises rate-releasing polymers such as xanthan gum. The antibiotic is present in a concentration of 71.43 %w/w of the tablet and the polymer is present in concentration of 1.07 % w/w (example 2, table 3). The total weight of the tablet is 1400 mg with the antibiotic taking up 1000 mg. The reference further comprises cross-linked polyvinylpyrrolidone, magnesium stearate and talc.

The only deficiency in the reference is the recitation of a different yet equally effective antibiotic agent. Ciprofloxacin and erythromycin, along with its' derivatives are well known

antibiotics. Substituting and interchanging these compounds is well within the level of ordinary skill in the art. As seen in Fuisz, which discloses a controlled release formulation where erythromycin and ciprofloxacin are listed as possible bio-effective agents (col. 8, lin. 20 – 30; claim 5). The composition also comprises rate-controlling polymers and other additives, such as hydroxypropylmethylcellulose (col. 10, lin. 13 – 38).

Ayer et al discloses a controlled release formulation where erythromycin and ciprofloxacin are possible bio-effective agents (example 4; col. 11, lin. 65 – 67). The dosage form further comprises the acrylic polymer Carbopol as a polymeric component (col. 15, lin. 25 – 30).

Misra et al discloses a controlled release formulation where clarithromycin and ciprofloxacin are listed as possible bio-effective agents (col. 8, lin. 53 – col. 10, lin. 29; col. 12, lin. 35 – 38). The formulation further comprises rate-controlling polymers such as cellulose derivatives (col. 12, lin. 10 – 15).

With this taken into consideration, one of ordinary skill in the art would have been motivated to combine the teachings of the references. A skilled artisan would have been motivated to substitute the similar active agents of the reference into the formulation of Talwar, using the method of Talwar, in order to impart antibiotic properties on the formulation. Talwar provides the teachings that a monolithic dosage form is possible of antibiotics such as ciprofloxacin and erythromycin derivatives. There would have been a reasonable level of expectation at the time of the invention, which would have resulted in a monolithic single dosage of clarithromycin.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
March 12, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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